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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/368,630	08/05/1999	DAVID M. CENTER	12875	5759

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EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	22

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/368,630	CENTER ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 November 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): *See Continuation Sheet*.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowable: *2-33*.

   Claim(s) objected to: _____.

   Claim(s) rejected: *35*.

   Claim(s) withdrawn from consideration: _____.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claims 2-33 and 35 under 35 U.S.C. § 112, second paragraph and the rejection of claims 2-33 under 35 U.S.C. § 112, first paragraph (enablement)..

Continuation of 5. does NOT place the application in condition for allowance because: Claim 35 is rejected under 35 U.S.C., first paragraph (enablement) and is directed to a pharmaceutical composition comprising an isolated IL-16 antagonist peptide and a pharmaceutically acceptable carrier. Applicant's arguments (Paper No. 21, 06 November 2002) have been fully considered but are not deemed persuasive in part for the following reasons. Applicant asserts that a principle feature of the invention resides in the recognition of the antagonistic activities of peptides which substantially correspond to the C-terminal sequence of a full length IL-16 molecule. Applicant argues that the specification teaches that an IL-16 antagonist peptide can be used in the treatment of an IL-16 mediated disorder. Applicant admits that those skilled in the art may need to conduct additional experimentation to optimize the dosage and route of administration of a peptide in connection with treatment of a disorder, but such additional experimentation is routine to those skilled in the art. Applicant also provides a declaration under 37 CFR 1.132 as evidence of the routine nature of additional experiments.

Applicant's arguments have been fully considered but are found to be persuasive in part. The evidence in the declaration of Christopher Martin under 37 CFR 1.132 is persuasive in part. The declaration indicates the effects of the peptide of SEQ ID NO: 24 on antigen-induced early and late airway responses, airway hyperresponsiveness and airway inflammation in sheep. Therefore, the specification, while being enabling for a pharmaceutical composition comprising the isolated IL-16 antagonist of SEQ ID NO: 24 and a pharmaceutically acceptable carrier, does not reasonably provide enablement for a pharmaceutical composition comprising any isolated IL-16 antagonist peptide of claims 2-4, 6, 14, or 22 and a pharmaceutically acceptable carrier. The assumption that other 4-mer, 8-mer, and 16-mer IL-16 antagonist peptides would have biological activities similar to the antagonist peptide of SEQ ID NO: 24 cannot be accepted in the absence of supporting data. Certain positions in the amino acid sequence are critical to a protein's structure/function relationship and it cannot be determined from the submitted declaration if any of the other IL-16 antagonist peptides retain the same structure/function properties of the peptide of SEQ ID NO: 24 to be able to treat a disorder or disease in an animal.

(Please note, as mentioned above, the specification is enabling for a pharmaceutical composition comprising the isolated IL-16 antagonist of SEQ ID NO: 24 and a pharmaceutically acceptable carrier. This enablement issue could be overcome by amending/adding a claim to recite "A composition comprising the isolated peptide of any of claims 2-4, 6, 14, or 22 and an acceptable carrier".)